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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,803

01/14/2005

Robert Lange

Q83451

6807

23373 7590 04/24/2009
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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

04/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,803	Applicant(s) LANGE, ROBERT	
	Examiner JERRY CUMBERLEDGE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kambin (US Pat. 5,584,887) in view of McMillan (US Pat. 5,556,687).

Kambin discloses a longitudinal implant (Fig. 15, ref. 82) and connecting device (Fig. 15, ref. 60) wherein said longitudinal implant is fastenable to bones on either side of a damaged area through said connecting device (Fig. 16), said implant and connecting device comprising: a longitudinal implant (Fig. 15, ref. 82) and a connecting device (Fig. 15, ref. 60), said connecting device is operative to squeeze and lock the longitudinal implant into position and wherein the implant is one of an elongated structure (Fig. 15), the structure having a longitudinal slot (Fig. 15, middle slot) extending along a substantial portion of its length (Fig. 15) and wherein the implant is formed without any recesses bevels, or slants, adjacent to the longitudinal slot (Fig. 15).

Kambin discloses the claimed invention except for the longitudinal implant being made of a filament or fiber composite material, wherein filaments or fibers in said material are oriented to resist biomechanical forces, a connecting device being made of a material harder than the longitudinal implant and wherein the filaments or fibers are aligned lengthwise, so that compression will not change their strength characteristics to

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any extent even when compressed and wherein the implant; the longitudinal implant is made of a carbon filament composite material. The filaments are encapsulated in a polymer matrix. The filaments are encapsulated in PEEK or PEKEKK. The connecting device comprising a pedicle screw having an upper section having a width greater than the width of said slot and an exteriorly threaded portion extending outwardly from said section and extending through said slot; the screw and connecting device each are made of titanium; the filaments are woven, comprising first filaments that are oriented in axial direction of the implant, and a second filaments that are oriented perpendicular to the axial direction of the implant.

MacMillan discloses a longitudinal implant (Fig. 1, ref. 10), made of a filament or fiber composite material (column 4, lines 43-53), wherein filaments or fibers in said material are oriented (column 7, lines 65-67) to resist biomechanical forces (column 8, lines 1-2); a connecting device (Fig. 2, ref. 20) made of a material harder than said longitudinal implant (column 3, lines 32-35) and wherein the filaments or fibers are aligned lengthwise (column 7, lines 65-67 and column 8, lines 1-2), so that compression will not change their strength characteristics to any extent even when compressed and wherein the implant; the longitudinal implant is made of a carbon filament composite material (column 4, lines 28-29). The filaments are encapsulated in a polymer matrix (column 4, lines 56-58). The filaments are encapsulated in PEEK or PEKEKK (column 4, lines 62-67); the screw and connecting device each are made of titanium (column 3, lines 32-35); and the filaments are woven (Fig. 6, ref. 102)(column 4, lines 37-42). The use of the composite material is advantageous in that it resists splitting of the bone plate

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(column 2, lines 4-7) and resists bending of the bone plate (column 2, lines 7-10).

Furthermore, the use of composite materials in a bone plate can be helpful in preventing stress shielding (column 2, lines 21-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the longitudinal implant of Kambin with the features as disclosed by MacMillan in order to allow the implant to resist splitting (column 2, lines 4-7) and resist bending (column 2, lines 7-10). Furthermore, the use of composite materials in a bone plate can be helpful in preventing stress shielding (column 2, lines 21-22).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kambin (US Pat. 5,584,887) in view of McMillan (US Pat. 5,556,687) in view of Törmälä et al. (US Pat. 5,084,051).

Kambin in view of McMillan disclose the claimed invention except for the implant being a rod.

Törmälä et al. disclose an implant in the shape of a rod (Fig. 8)(column 11, lines 47-51) comprising a fiber reinforced composite material (column 11, lines 52-54), which can be used as fixation devices in the treatment of cancellous bone fractures, osteotomies and arthrodesis (column, 11, lines 47-51).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the longitudinal member of Kambin in view of McMillan as a rod as taught by Törmälä et al., in order to use the implant in the

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treatment of cancellous bone fractures, osteotomies and arthrodesis (column, 11, lines 47-51).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kambin (US Pat. 5,584,887) in view of McMillan (US Pat. 5,556,687) in view of Eisermann et al. (US Pub. 2002/0123750 A1).

Kambin in view of McMillan disclose the claimed invention except for the filaments comprising first filaments that are oriented in an axial direction of the implant, and second filaments that are oriented perpendicular to the axial direction of the implant.

Eisermann et al. disclose an implant (Fig. 4, ref. 90) comprising filaments (Fig. 4, ref. 98) that are oriented in an axial direction of an implant (Fig. 4, filaments extending from left to right) and second filaments (Fig. 4, filaments extending from top to bottom) that are oriented perpendicular to the axial direction of the implant (Fig. 4)(paragraphs 0032 and paragraph 0033), in order to allow the implant to have similar tensile properties in the x and y directions (paragraph 0032).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the implant of Kambin in view of McMillan with the filaments comprising first filaments that are oriented in an axial direction of the implant, and second filaments that are oriented perpendicular to the axial direction of the implant as taught by Eisermann et al., in order to allow the implant to have similar tensile properties in the x and y directions (paragraph 0032).

Response to Arguments

Applicant's arguments filed 02/26/2009 have been fully considered but they are not persuasive.

Regarding Applicant's argument that there is no disclosure of the depression and locking feature, the examiner notes that this feature is being claimed functionally. Claim 13 states "...wherein, said connecting device is operative to squeeze and lock the longitudinal implant into position both by depression caused by squeezing and increased friction between the harder material of the connecting device and the composite material of the longitudinal implant.." The examiner notes that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). In this case, the connecting device is capable of squeezing and locking the longitudinal implant into position both by depression (caused by the pressing of ref. 60 against ref. 82 by the use of the nut of ref. 86). The nut will engage ref. 66, pulling reference 60 into abutment with reference 82 and pressing them together, creating a squeezing force between reference 60 and reference 82. As the force of friction increases with an increased force between two surfaces, the action of reference 86 with reference 60 is also capable of creating a frictional force between reference 60 and 82 as it squeezes them together.

Regarding Applicant's assertion that, logically, if one were to use the motivation from the office action to modify the Kambin reference, one would also have included the spherical formation of McMillin, the examiner respectfully disagrees. The examiner notes that in the Summary of the Invention section of McMillan's specification, McMillan discloses that it is the fibers that resist the splitting of the plate (column 2, lines 1-10). The recesses are not even mentioned in the Summary section by McMillan. Furthermore, the recesses are described by McMillin as helping to prevent splitting, but are not referred to as being required to prevent splitting of the bone plate. It is rather the fibers that are the main component of the anti-splitting mechanism, as discussed in the Summary section.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733